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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/806,515 | 03/22/2004 | Tom F. Lue | 220022001610 | 3893 |

25225 7590 11/15/2006

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| EXAMINER | |
|---|---|
| QIAN, CELINE X | |
| ART UNIT | PAPER NUMBER |
| 1636 | |

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/806,515 | LUE ET AL. | |
| | Examiner | Art Unit | |
| | Celine X. Qian Ph.D. | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4,5,9,11-15 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,9,11-15 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1206, 0704, 0805, 0406, 0606
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1, 4, 5, 9, 11-15, 21-28 are pending in the application.

### *Election/Restrictions*

Applicant's election without traverse of Group I in the reply filed on 10/6/06 is acknowledged.

Accordingly, claims 1, 4, 5, 9, 11-15, 21-28 are currently under examination.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 9, 11-15, 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the relative skill of those in the art; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue" (MPEP 2164.01 (a)).

The nature of the invention is a method of treating or preventing either male erectile dysfunction or female arousal disorder by administering bFGF to the patient.

The state of art at the time of filing teaches that male erectile dysfunction may be the result of either psychological or physiological factors or both. Physiological factors that can cause male erectile dysfunction include hormonal insufficiency, nerve dysfunction, arterial insufficiency or venous leakage. Each of these factors alone or in combination may contribute to the erectile dysfunction. The female arousal disorder is also a multi-causal and multi-dimensional medical problem. This disorder is defined as the persistent or recurring inability to attain, or maintain adequate sexual excitement causing personal distress. The conditions can either be the result of psychological factors or physiological conditions including diminished vaginal/clitoral blood flow, altered hormonal milieu, prior pelvic trauma and use of medications such as serotonin re-uptake inhibitors (Goldstein, 2000, International Journal of Impotence Research, 12, supp. 4, S152-S157). Goldstein further discuss the physiology and molecular mechanism female arousal process which involves cGMP signaling pathway and NO, NPY and PDE appear to be important factors involved in this process. However, the prior art appears to be silent on whether bFGF is effective in prevent or treating male erectile disorder or female arousal disorder.

The breadth of the claims is very broad. The broadest claim encompasses a method for preventing and treating erectile dysfunction caused by any factor (include both psychological or physiological) by administering bFGF by any route of administration. The claim also encompasses a method for preventing and treating female arousal dysfunction caused by any factor by administering bFGF.

The teaching of the specification is limited. The specification only provides a rat model for treating male erectile dysfunction caused by damaging cavernous nerve by intra-cavernous injection of nucleic acid encoding VEGF, BDNF or a combination thereof. The specification does not teach whether bFGF prevent or treat male erectile dysfunction as a result of cavernous nerve damage. The specification also fails to teach whether bFGF can prevent or treat erectile dysfunction caused by other factors such as arterial insufficiency or venous leakage. Moreover, the specification fails to teach whether administering bFGF to female patients with sexual arousal disorder can provide treatment to those patients. Further, the specification also fails to teach whether administering bFGF to normal female would prevent future occurrence of sexual arousal disorder. Lastly, the specification does not demonstrate that any route of administration would result in the treatment of the erectile dysfunction.

Given the complexity of the cause and molecular mechanism of both the erectile dysfunction and female sexual arousal disorder, the importance of route of administration, whether administering a single factor bFGF by any route would be effective in treating or preventing all types of erectile dysfunction or female arousal disorder is unpredictable. Based on the data provided in the specification, whether administering bFGF to an individual can prevent or treat the claimed disorder is unpredictable because the specification fails to show or providing any working example that administering bFGF to an animal model would prevent or treat the claimed said disorder. Therefore, one skilled in the art would have to engage in undue experimentation to practice the method commensurate in scope with the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN PH.D.
PRIMARY EXAMINER